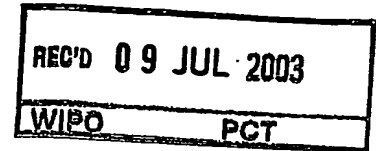


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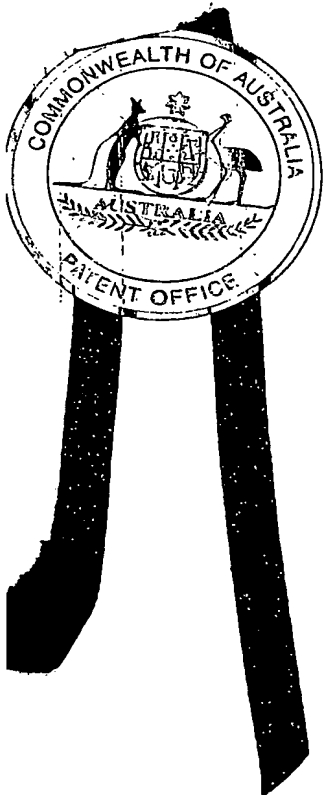


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I, LEANNE MYNOTT, MANAGER EXAMINATION SUPPORT AND
SALES hereby certify that annexed is a true copy of the Provisional specification
in connection with Application No. PS 3138 for a patent by RIANCORP PTY
LTD as filed on 25 June 2002.



WITNESS my hand this
Third day of July 2003

LEANNE MYNOTT
MANAGER EXAMINATION SUPPORT
AND SALES

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RIANCORP PTY. LTD.

AUSTRALIA

PATENTS ACT 1990

PROVISIONAL SPECIFICATION FOR THE INVENTION ENTITLED:

"LASER BEAM HOMOGENISERS IN MEDICAL APPLICATIONS "

This invention is described in the following statement:

This invention relates to laser systems and in particular to lasers used in the medical field.

BACKGROUND

- 5 Safety when using or being exposed to lasers is a very important consideration. International Standards exist with regards to the classification of laser devices and the way in which different classes of laser can be used. Those laser devices that conform to the class 1 definition are considered the safest.
- 10 Laser emitting devices that do not fall within the class 1 definition require the device and the user, and in medical applications the patient, to use or be subject to one or more of the following: use of safety spectacles, interlock systems, warning lights, etc.
- 15 Laser emitting devices have a wide range of wavelength, energy and pulse characteristics and the classification system is a guide as to the way in which each device having one or more of those characteristics can be used and by whom the device can be used.
- 20 A class 1 laser-emitting device can be used without restriction but in accordance with the manufacturer's instructions for the purpose for which it was designed. This means that special training and additional safety equipment is not required. Thus operating costs are less when compared to the attendant operating costs of other classes of laser-emitting devices.
- 25 A major consideration when designing laser-emitting devices is the amount of power that the source laser in the device is required to emit so as to provide adequate laser emission power from the laser device. One of the determinants of this characteristic is the required power density to be delivered at the application site over a desired area.
- 30 As the area required to be treated increases for a required power density so does the power of the source laser needed to support that requirement.

Apart from the power, pulse parameters and wavelength of the laser another of the critical features in specifying the class of the laser is the apparent aperture of the laser source. The apparent aperture will determine the image size that the laser source can form for example on the retina of an inadvertent observer.

5

The requirement specification described above is sometimes referred to as the apparent source and it is this characteristic that is used to determine the class of the laser-emitting device.

- 10 Current laser device configurations are restricted somewhat by the physics of the devices used to generate the source laser. For diode laser sources, the emitting aperture (the area of the spot beam) of the laser radiation is typically 7×1 microns for a 904 nanometer Gallium Arsenide (Ga-As) laser diode. These devices typically have pulsed outputs with 1 and 5 Watt peak powers with the pulse repetition and duration being
- 15 variable to suit the application. There are many other laser diode configurations, the device type described above is an example of such devices.

In some applications it is desired to not only provide the laser radiation over a larger area but also to control the power density thus requiring an adequately high power

20 laser source.

It is an aim of the invention described herein to provide a laser emitting device that meets not only a desired power density and spot area requirement, but that meets class 1 requirements thus providing long term minimization of the running costs of the

25 device.

BRIEF DESCRIPTION OF THE INVENTION

In a broad aspect of the invention a laser emitting device comprises a laser source that is located a predetermined distance from an optical homogeniser device adapted to

30 modify the apparent aperture of said laser source to a predetermined characteristic.

Specific embodiments of the invention will now be described in some further detail with reference to and as illustrated in the accompanying figures. These embodiments are illustrative, and not meant to be restrictive of the scope of the invention. Suggestions and descriptions of other embodiments may be included within the scope of the invention but they may not be illustrated in the accompanying figures or alternatively features of the invention may be shown in the figures but not described in the specification.

BRIEF DESCRIPTION OF THE FIGURES

Fig 1 depicts a generic arrangement of a preferred laser-emitting device according to the invention.

DETAILED DESCRIPTION OF AN EMBODIMENT OF THE INVENTION

Although a particular medical application is described herein and a particular laser emitting device configuration is also described, it should be understood that these details are illustrative only and not meant to be limiting in any way upon the application or configuration of the principle of the invention.

In the medical field, low power level laser radiation is known to have beneficial medical effects in some disease and restorative therapies.

One example is the treatment of lymphoedema other examples include cauterizing visible veins and port wine markings on the skin. A yet further example is laser keratectomy (ablation/sculpturing of the surface of the retina).

Clearly, the frequency, power level (continuously on or modulated on/off duty cycle of the radiation at the same or changing levels) and characteristics of the laser are determined by the nature of the treatment outcome desired by a clinician.

The area of effective laser irradiation on the relevant tissue or organ of the patient is a matter of design and specification by the clinician.

In a preferred arrangement the laser source is a Gallium Arsenide Laser diode having an emitting aperture of 7×1 microns of 904 nanometer wavelength is 5-Watts peak power. In a Lymphoedema application the laser output is modulated or controlled to have a low 2,500 Hz and high 5,000 Hz repetition rate of 200-nanosecond duration. Such a device falls near the class 1 and adjacent class 111B boundary.

In this type of medical procedure the operator holds the laser-emitting device so that the apparent aperture is moved in a predetermined path over the patient's treatment area. The treatment area is usually the tissue in near vicinity of the potentially or actually diseased lymph nodes, under the patients arm or the groin area are examples of treatment sites.

There is exists a slight divergence of the laser beam which is factored into the design, the amount of divergence being directly proportional to the distance between the output aperture of the laser diode and the patient's treatment site.

The invention includes the use of an optical homogeniser such as for example a CORNING™ high performance microlens array. A specification of its characteristics includes that it is made from either fused silica, silicon or polymer-on-silica. It has a center to center spacing tolerance of less than 1 micrometer and a total run-out over 50mm of less than 7 micrometers. It has a maximum array size of 50mm by 50mm, a maximum substrate diameter of 150mm and minimum substrate thickness of 400 micrometers. It has a maximum array size of less than 7 micrometers. It has a maximum array size of 50mm by 50 mm, a maximum substrate diameter of 150mm and minimum substrate thickness of 400 micrometers.

Characteristics of the microlens are as follows. It can be spherical or aspherical and is designed with a polymer surface irregularity less than one quarter of a wavelength at 633 nanometers in at least 97% the lens is silicon oxide (SiO_2) the surface irregularity is less than one half of a wavelength at 633 nanometers.

A focal length in air between 1.5mm and 6.0mm at greater than or equal to 200 micrometers. The focal length tolerance in air with polymer is plus or minus 10 micrometers within the array and plus or minus 25 micrometers array to array. While the focal length tolerance in air with SiO₂ is plus or minus 50micrometers with an array to array.

Clear aperture dimension is less than or equal to 1.3 mm and surface roughness is less than 100 Angstroms A°(Ra). The operating temperature is permitted to be between 0 and 70°C.

The surface relief diffuser version of the microlens array is used in preferred arrangements that are designed to spread light in a predetermined gain distribution. Both symmetric and asymmetric surface relief diffusers can be used dependent on the application. This is not the only type of homogeniser that can be used, there are other fabrication techniques such as holographic diffusers. The important aspect is that the homogeniser acts like a near perfect diffuser thus causing the apparent aperture to be the homogeniser not the aperture of the emitting device.

In the subject application the apparent aperture of the source laser device is made uniformly larger to the order of 6mm².

The preferred distance between the laser source aperture and the optical homogeniser is 5mm. This accounts for the divergence of the source laser beam and as a result the apparent aperture and power distribution is such that the full device falls well within class 1 limits.

Fig. 1 displays the laser source 10 and a diffuser element 12 located a distance D1 from the laser source. The slightly divergent laser beam 14 from the source is exaggerated for the purpose of illustration only. The resultant laser beam power distribution is pictorially shown at 16 a distance D2 from the diffuser element.

Having the arrangement described allows for the power output of the source laser to be increased allowing the ideal required power distribution to be homogeneously distributed over a much greater area than would otherwise be the case. This in turn allows the total laser-radiating device to remain within the class 1 laser classification.

5 This ultimately reduces cost to the patient.

A larger area can be treated at the same time, thus reducing treatment time and complexity of movement. This further benefits the patient, as the period of potential discomfort is minimized.

10

It will be appreciated by those skilled in the art that the invention is not restricted in its use to the particular application described. Neither is the present invention restricted in its preferred embodiment with regard to the particular elements and/or features described or depicted herein. It will be appreciated that various modifications can be made without departing from the principles of the invention. Therefore, the invention should be understood to include all such modifications within its scope.

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Dated this 25th day of June 2002

RIANCORP PTY LTD

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By its Patent Attorneys
MADDERN



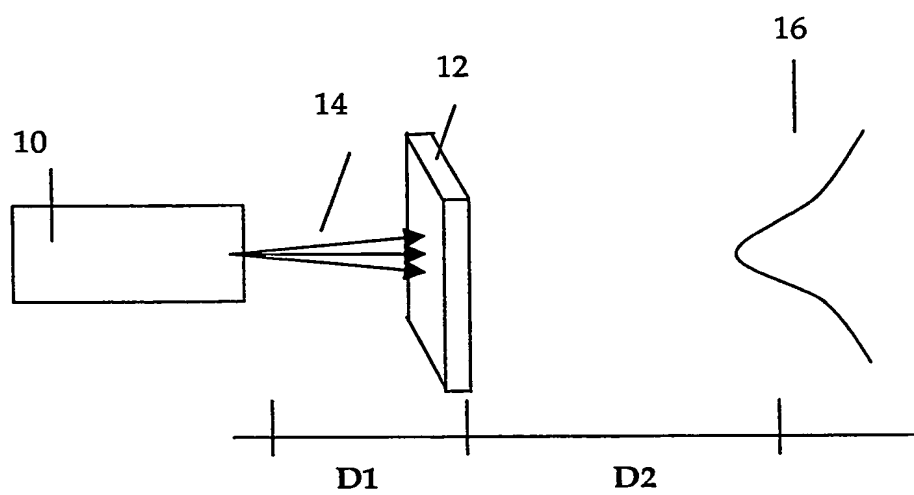


Fig. 1